

## **REMARKS**

### **Status of Claims**

Claim 35 is currently amended.

Claims 2, 30 and 38 are canceled.

Claims 1 and 3-29 and 31-37 are pending.

### **Drawings**

In the Office Action the drawing is objected to under 37 C.F.R. § 1.823(a). It is said that the species in claim 38 involving stimulating the patient's stomach must be shown or the feature canceled from the claims. Applicants believe that this objection is obviated by the cancellation of claim 38.

### **Specification**

The specification is objected to by the Office as failing to provide proper antecedent basis for the claimed subject matter. It is said that the limitation of claim 38 involving indirect application of stimulation to the right and left vagi by stimulating the stomach or other visceral organ is not found. Applicants have chosen to cancel claim 38 without prejudice, and are amending the "Summary of the Invention" section of the specification to recite the embodiment of claim 38. This ground of objection is moot in view of the cancellation of claim 38.

### **Double Patenting**

Claims 1 and 3-38 are rejected in the Office Action for nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,587,719. This rejection is moot with respect to now-canceled claims 30 and 38. Applicants will submit an appropriate Terminal Disclaimer to obviate this nonstatutory obviousness-type double patenting rejection. It is respectfully requested that the requirement for the Terminal Disclaimer be held in abeyance until the claims are otherwise considered to be allowable.

### **Claim Amendments**

Applicants have chosen to cancel claims 30 and 38 without prejudice.

### **Claim Rejections Under 35 U.S.C. § 103(a)**

Claims 1 and 3-38 are rejected in the Office Action of April 5, 2006 as being unpatentable over *Kim et al.* (U.S. Pat. No. 5,514,175) in view of *Zabara* (U.S. Pat. No. 5,540,734). The Office takes the position that although *Kim et al.* do not directly stimulate the right and left vague nerves, a person of ordinary skill in the art given the disclosure of *Kim et al.*

would have seen the obviousness of directly applying the stimulus to the nerves to effect obesity control because it is of general knowledge in the art that nerves may effectively be stimulated either indirectly through the skin with an external stimulator unit, or directly through the use of an implanted electrode and/or stimulator. In the Office Action, it is suggested that "a stimulated nerve is a stimulated nerve, regardless of where the stimulation originated."

In response, Applicants respectfully traverse. In order to make the proposed modification of *Kim et al.*, it would have required eliminating certain essential features of their method and device. An express objective of the method disclosed by *Kim et al.* is to provide a method for treating patients using a portable and unobtrusive embodiment of the low voltage apparatus described therein (col. 2, lines 43-55) by using a particular externally applied auricular stimulator (col. 3, lines 3-13). Moreover, the method of *Kim et al.* contemplates only the external (indirect) application of stimuli to auricular points and/or post-auricular points (col. 3, lines 22-24; col. 4, lines 37-41).

The MPEP § 2143.01 requires that there be a suggestion or motivation to modify the references, that the prior art must suggest the desirability of the claimed invention (§ 2143.01 I), that the proposed modification cannot render the prior art unsatisfactory for its intended purpose (§ 2143.01 V), and the proposed modification cannot change the principle of operation of a reference (§ 2143.01 VI).

In the instant matter, there is no teaching in *Kim et al.* to modify the portable external auricular stimulator and related method of use to provide for direct, instead of indirect or externally applied stimulation of the vagus nerve. Even if one of ordinary skill in the art at the time Applicants' invention was made had been aware that the vagus nerve could be stimulated via implantable or external neurostimulating devices, as taught by *Zabara* (col. 1, lines 28-32), this would not make up for the lack of teaching in *Kim et al.* to make the proposed modification. The skilled person would not have been motivated to alter the device and method of *Kim et al.* to provide the claimed direct stimulation because such modification would have been contrary to the explicit and implicit design of *Kim et al.*'s method and device, as noted above. Moreover, the skilled person would be disinclined to subject the patient to the discomfort of a surgical implantation procedure, as would be required for direct stimulation, particularly for potentially long term (chronic) treatment (as required in claim 3), if the existing method and apparatus of

*Kim et al.* could effect vagal stimulation externally via the patient's ears to achieve the therapeutic goal of treating obesity. Table I (col. 7, lines 27-29) and col. 8, lines 7-12 of *Kim et al.* indicate that their externally applied therapy was successful. This militates against the desirability of changing, and possibly destroying the existing design and therapeutic method of *Kim et al.* For at least the foregoing reasons, the invention of claims 1, 3-29 and 31-37 would not have been obvious to one of ordinary skill in the art at the time Applicants' invention was made over *Kim et al.* in view of *Zabara* in combination with the knowledge of one of skill in the art at the time Applicants' invention was made. This rejection is moot with respect to claim 38, which has been canceled without prejudice.

### Conclusion

Reconsideration of the application and withdrawal of the objections and rejections are requested in light of the foregoing amendments and/or remarks. Applicants respectfully request allowance of all pending claims. This is believed to be a full and complete response to the Office Action dated April 5, 2006. If any issue in the Office Action has been overlooked or is deemed to be incompletely addressed, Applicants respectfully request the opportunity to supplement this response. It is believed that no extensions of time or fees are required, beyond those that may otherwise be provided for in documents accompanying this paper. In the event that any additional extension of time is necessary to allow consideration of this paper, such extension is hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required (including fees for net addition of claims) are hereby authorized to be charged to Deposit Account Number 503053 of Cyberonics, Inc., Houston, Texas.

08/07/06

Date

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R. Elizabeth Skaggs

(Name of person making deposit)

R. Elizabeth Skaggs

(Signature)

Respectfully submitted,

Timothy L. Scott

Timothy L. Scott

Reg. No. 37,931

Cyberonics, Inc.

100 Cyberonics Blvd.

Houston, Texas 77058

Phone: (281) 727-2652

Fax: (281) 853-2505